K012506

MAR 7 2002

Medtronic Sofamor Danek
MasterGraft™ Bone Void Filler
510(K) Summary
March 2002

I. **Company:** **Medtronic Sofamor Danek USA**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proposed Proprietary Trade Name:** MasterGraft™ Bone Void Filler

III. **Product Description**

MasterGraft™ Bone Void Filler is made of medical grade combination of hydroxyapatite and β-tricalcium phosphate. MasterGraft™ is provided in a 60 percent hydroxyapatite and 40 percent β-tricalcium phosphate formulation. Alternatively, MasterGraft™ may be provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation. The product is supplied sterile for single patient use. MasterGraft™ is an osteoconductive porous implant.

IV. **Indications**

MasterGraft™ Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. MasterGraft™ Bone Void Filler is to be gently packed into bony voids of the skeletal system (e.g., the spine, pelvis, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MasterGraft™ provides a bone void filler that resorbs and is replaced with bone during the healing process.

V. **Substantial Equivalence**

Documentation was provided which demonstrated the MasterGraft™ Bone Void Filler to be substantially equivalent to other previously cleared bone void fillers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 2002

Richard W. Treharne, Ph.D.
Sr. Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K012506
MasterGraft™ Bone Void Filler
Regulatory Class: unclassified
Product Code: MQV
Dated: December 5, 2001
Received: December 7, 2001

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012506

510(k) Number (if known): K012506

Device Name: **MasterGraft Bone Void Filler**

Indications for Use:

MasterGraft™ Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. MasterGraft™ Bone Void Filler is to be gently packed into bony voids of the skeletal system (e.g., the spine, pelvis, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MasterGraft™ provides a bone void filler that resorbs and is replaced with bone during the healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)
(Optional 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012506